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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,931	07/25/2003	Dean A. Klein	54459-277675	5405
25764 7590 03/23/2007 FAEGRE & BENSON LLP PATENT DOCKETING 2200 WELLS FARGO CENTER 90 SOUTH SEVENTH STREET MINNEAPOLIS, MN 55402-3901			EXAMINER JASANI, ASHISH S	
			ART UNIT 3737	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/626,931	Applicant(s) KLEIN ET AL.	
	Examiner Ashish S. Jasani	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-78 have been considered but are moot in view of the new ground(s) of rejection.

The office introduces McCrory et al. (US 2001/0004395) which teaches of a permanent fiducial marker.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the elements of claims 1-78 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-32, and 42-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (USPN 6394965) in further view of McCrory et al. (US 2001/0004395)

With regards to claims 1, 2, 4-13, 22, 23, 24, 27, 42, 46-48, 49-56, 70, and 77; Klein teaches of tissue marking using microparticles (abstract). Klein teaches of "implanting at least one permanent marker" such that "delivery of microparticles using a needle and syringe allows very precise delivery of microparticle markers to a desired tissue site, this is particularly true if a biopsy probe used to perform a biopsy is used to assist delivery of microparticles for tissue marking, without first moving the biopsy sheath" (column 2, lines 54-59). Klein teaches of imaging such that "the detectable component, e.g., contrast-enhancing agent, can be any material capable of enhancing contrast in a desired imaging modality (e.g. magnetic resonance, X-ray, ultrasound, magnetotomography, electrical impedance imaging, light imaging (e.g. confocal

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microscopy and fluorescence imaging) and nuclear imaging (e.g. scintigraphy, SPECT and PET))" (column 4, lines 6-13). Klein teaches of treating the site such that "the invention provides methods of marking tissue for any reason, such as to mark the site of the removal of a tissue, e.g., the removal of a polyp from a colon or rectum; to mark the site of a biopsy, including a breast biopsy, a prostate biopsy, a colon biopsy, a rectum biopsy; or to mark the site of any other medical procedure or removal of tissue or biopsy at another tissue location" (column 3, lines 52-58). Klein teaches that the contrast enhancement can be for a number of imaging modalities, but does not teach that the contrast agent is multimodal.

McCrorry et al. teaches of an implantable, permanent fiducial marker (abstract). McCrorry teaches that the fiducial marker is a multi-modal marker (§ 10). McCrorry teaches that the marker is imageable via MRI, CT, and Ultrasound (§ 34).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to combine the Klein biopsy marking method with the McCrorry et al. multimodal contrast agent to enhance diagnosis with multiple imaging modalities and to register the image (§ 6-8).

With regards to claim 3, McCrorry teaches of not using solid metal (Claim 20) for it will cause unwanted distortion (§ 35).

With regards to claims 14, 17-19, 21, and 25; Klein teaches of monitoring such that "The tissue may be marked for any reason, for example to return to the same tissue site to monitor the progress of a medical condition or a treatment, or to perform a subsequent biopsy at the same site" (column 3, lines 58-62).

With regards to claims 15, 16, and 26; Klein teaches of mapping and radiation therapy such that “ the tissue may be marked to provide a target for radiation treatment, i.e., detectable microparticles can be delivered to a tissue site to act as a target at which or near a beam of radiation can be precisely directed” (column 3, lines 62-65).

With regards to claim 20, Klein teaches of guiding such that “the tissue may be marked for any reason, for example to return to a the same tissue site to monitor the progress of a medical condition or a treatment, or to perform subsequent biopsy” (column 3, lines 58-61).

With regards to claim 28, McCrory et al. teaches of MRI, CT, and ultrasound which can all be electronic portal imaging; McCrory et al. teaches of CT or X-ray which can be portal film imaging.

With regards to claims 29-32 and 78, Klein teaches of a “biologically active agent” of beta-glucan such that “the microparticles can be delivered using a fluid carrier, which can be any biologically compatible material capable of delivering the microparticles to a desired tissue site, such as a biologically compatible suspension, solution, or other form of a fluid or gel” (column 2, lines 41-45. Klein goes on to teach of the carrier being that of beta-glucan (column 8, lines 58-61).

With regards to claim 33-34, McCrory et al. teaches of multi-modal image registration (¶ 6-8).

With regards to claim 35-41, Klein teaches of performing radiation therapy (column 3, lines 62-65). McCrory et al. teaches of radiation therapy such that “A permanently implanted marker allows comparison of scans over time for follow-up

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therapy (for example, to make lesion volume comparisons in order to monitor growth). It also allows fractionated radiotherapy, in which small doses of radiation are administered frequently over the course of treatment” (¶ 11).

With regards to claim 42, Klein teaches of implanting a marker (column 2, lines 10-23), imaging from a number of modalities (column 3, lines 34-41), and treatment (column 3, lines 51-65).

With regards to claim 43-44, Klein teaches of monitoring the treatment site such that “the tissue may be marked for any reason, for example to return to a the same tissue site to monitor the progress of a medical condition or a treatment, or to perform subsequent biopsy” (column 3, lines 58-61). A biopsy is a removal of tissue.

With regards to claim 45, Klein teaches of breast biopsy (column 3, line 54) in which it is well known in the art that it can be imaged via MRI, CT or X-Ray, and Ultrasound (¶ 34).

With regards to claim 57-59, Klein et al. teaches of aluminum oxide and zirconium oxide (column 2, lines 37-40).

With regards to claims 60-63 and 73, Klein teaches of a biocompatible pyrolytic carbon surface (abstract).

With regards to claim 64-66, Klein teaches that the particles can have a size of 1000 microns (column 2, lines 17).

With regards to claims 67-68, McCrory teaches of a tube (Figure 1b).

With regards to claim 69, McCrory teaches of a liquid reservoir (¶ 34).

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With regards to claim 71, Klein teaches that the particle can be radiopaque (column 2, line 21).

With regards to claim 72, Klein teaches of additional material such that "Preferred paramagnetic metals include Gd (III), Dy (III), Fe (II), Fe (III), Mn (III) and Ho (III), and paramagnetic Ni, Co and Eu species. Preferred heavy metals include Pb, Ba, Ag, Au, W, Cu, Bi and lanthanides such as Gd, etc." (column 4, lines 57-60).

With regards to claim 74-76, Klein teaches of a beta-glucan suspension carrier which is biocompatible and derived from cell walls (column 8, lines 45-47).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ashish S. Jasani whose telephone number is 571-272-8025. The examiner can normally be reached on Mon. - Fri. 9:30 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272 - 4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASJ


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